DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
Washington DC 20420

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UNDER SECRETARY FOR HEALTH'S INFORMATION LETTER

SECURITY FOR RADIOACTIVE MATERIALS

1. This information letter has two purposes. The first purpose is to restate regulatory requirements for the security of radioactive materials. The second is to outline forthcoming security-related initiatives to ensure regulatory requirements are achieved.

2. The regulatory requirements for security are in Title 10 Code of Federal Regulations (CFR) 20.1801 and 10 CFR 20.1802. The regulations require a Veterans Health Administration (VHA) facility with a permit to receive, use, or store radioactive materials to secure the radioactive materials from unauthorized removal or access and to maintain constant visual surveillance for radioactive materials not in storage.

3. The National Radiation Safety Committee (NRSC) has a standing agenda item to review the status of security for radioactive materials at each committee meeting. One key element for the review is to evaluate the outcomes of Nuclear Regulatory Commission (NRC) and National Health Physics Program (NHPP) inspections. The attachment has a description of five recent inspections where a violation was cited for lack of compliance with 10 CFR 20.

4. Based on the NRC and NHPP inspection outcomes and other security reviews, the NRSC has developed the following security-related initiatives to ensure regulatory requirements are achieved:

a. NHPP must be required to focus on security during inspections at VHA facilities, and to complete annual security audits for facilities with larger activity sealed sources, such as irradiators and brachytherapy sealed sources;

b. Facilities must be required to dispose of or transfer disused sealed sources (i.e., sources not used for their intended clinical or research purpose for more than 24 months);

c. The feasibility of using two-delay methods (such as, locked door and source in a locked cabinet) for sealed sources in storage must be evaluated;

d. The availability of security-related information (i.e., newsletters, best practices, and frequently asked questions) on the NHPP intranet Web site must be increased;

e. A VHA-wide centralized inventory for sealed sources must be established; and,

f. Facilities must be required to complete a comprehensive evaluation of security for inspection outcomes that cite a Severity Level III violation, and to include security evaluation during periodic audits and annual program reviews.

5. The NRSC recognizes the increased focus on security requires a paradigm shift from the more traditional clinical emphasis to use radioactive materials for diagnosis and therapy to a concurrent emphasis to control access to radioactive materials or to have constant visual surveillance for those radioactive materials not in storage. Unfortunately, recent events in the United States dictate increased security for radioactive materials.

6. Attachment A presents the results of recent inspections as five case studies.

7. Any questions about this information letter or the security for radioactive materials should be referred to E. Lynn McGuire, Director, National Health Physics Program, at (501) 257-1571.

S/ Arthur S. Hamerschlag for
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Acting Under Secretary for Health

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ATTACHMENT A

RECENT INSPECTIONS – CASE STUDIES

NOTE: *All of the following are radionuclides used in medicine: ^{99}Mo, ^{99m}Tc, ^{125}I, ^{137}Cs, and ^{57}Co.*

1. Five recent Nuclear Regulatory Commission (NRC) and National Health Physics Program (NHPP) inspections have cited violations for failure to comply with Title 10 Code of Federal Regulations (CFR) 20.1801 or 10 CFR 20.1802. These regulatory requirements for security require a Veterans Health Administration (VHA) facility with a permit to receive, use, or store radioactive materials to secure the radioactive materials from unauthorized removal or access, and to maintain constant visual surveillance for radioactive materials not in storage.

2. A description of the recent inspections is outlined in the following five case studies:

a. **Case Study 1**

(1) The NRC completed a routine, unannounced inspection. During the inspection, the NRC inspector found a door left open and unattended. The door was to the hot laboratory where two curies ^{99}Mo in a ^{99}Mo generator, 20 millicuries ^{125}I in 52 brachytherapy sealed sources or seeds, and 60 millicuries ^{137}Cs in two sealed sources were located. A trained staff member was in the general clinical areas, though the staff member did not have constant visual surveillance of the door to the hot laboratory.

(2) The NRC issued a notice of violation October 31, 2003, to the VHA master materials license. The violation was a Severity Level III violation involving the failure to secure from unauthorized removal or limit access to permitted material in a controlled area, and the failure to control and maintain constant surveillance of this permitted material.

(3) The medical center corrective action included retraining, installing automatic door closers, increased audits and Department of Veterans Affairs (VA) Police Service foot patrols. The NRC completed a 6-month follow-up inspection in January 2004, and did not identify any violations.

b. **Case Study 2**

(1) The NRC completed a routine, unannounced inspection. During the inspection, the NRC inspector found a failure to maintain control and security of unit doses of ^{99m}Tc. As an example, the NRC inspector observed unsecured and unattended unit doses totaling 150 millicuries and 48 millicuries ^{99m}Tc in the stress imaging and patient injection rooms, respectively. The NRC inspector confirmed by interviews with the nuclear medicine staff that it was a common practice to leave unit doses unattended and unsecured in these two rooms.

(2) The NRC issued a notice of violation September 2, 2003, to the VHA master materials license. The violation was a Severity Level IV violation involving the failure to secure from unauthorized removal or limit access to permitted material in a controlled area, and the failure to control and maintain constant surveillance of this permitted material.

(3) The medical center corrective action included locking these doors and a committment to closing and locking the doors to the stress camera and patient injection rooms in the future when unit doses are unattended.

c. **Case Study 3**

(1) The NHPP completed a routine, unannounced inspection. During the inspection, the NHPP inspector found a ^{57}Co flood source in an unattended imaging room.

(2) The NHPP issued a notice of violation October 16, 2003, to the health care system. The violation was a Severity Level IV violation involving the failure to secure from unauthorized removal or limit access to permitted material in a controlled area, and the failure to control and maintain constant surveillance of this permitted material.

(3) The health care system corrective action included retraining and increased audits.

d. **Case Study 4**

(1) The NHPP completed a routine, unannounced inspection. During the inspection, the NHPP inspector found a ^{99m}Tc patient dose had been placed in an imaging room drawer and left unattended.

(2) The NHPP issued a notice of violation October 31, 2003, to the medical center. The violation was a Severity Level IV violation involving the failure to secure from unauthorized removal or limit access to permitted material in a controlled area, and the failure to control and maintain constant surveillance of this permitted material.

(3) The medical center corrective action included retraining.

e. **Case Study 5**

(1) The NRC completed a routine, unannounced inspection. During the inspection, the NRC inspector found a door to a closet in a waste storage area unlocked and unattended. In the closet was a storage cabinet, also unlocked, containing 100 mCi ^{137}Cs in disused brachytherapy sources.

(2) The NRC issued a Notice of Violation April 7, 2004, to the VHA master materials license. The violation was a Severity Level III violation involving a failure to secure from unauthorized removal or limit access to permitted material located in a room within the radiation safety office.

(3) This inspection finding resulted from three preventable failures: not having a lock on one of the doors to the storage room, not keeping the room under constant visual surveillance, and not having a separate locked storage cabinet. Correction of any of the three preventable failures would have precluded the violation.